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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/555,244

10/31/2005

Winfried Miller

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EXAMINER

ARIANI, KADE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/555,244 | Applicant(s) MILLER, WINFRIED | |
| | Examiner KADE ARIANI | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 28-33 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 28-33, and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments filed on March 19, 2008, has been received and entered.

Claim 34 has been cancelled.

Claims 1-25, 28-33 and 35-37 are pending in this application and were examined on their merits.

Continued Examination under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/2008 has been entered.

Applicant's arguments filed on 03/19/2008 have been fully considered but they are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 11 and 18, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-17, 23-25, 28-31, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenberg (US Patent No. 5, 569,458).

Claims 1-10, 12-17, 23-25, 28-31, 36 and 37 are drawn to a composition comprising one plant protease and/or one animal protease, vitamins (having antioxidant activity), selenium-containing substances, one flavonoid, polysaccharides, amino acids, coenzyme Q-10, and a method for administering to a patient in need for such a treatment.

Greenberg discloses a composition comprising bromelain, papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), selenium amino acid complex or chelates (selenium-containing substances), proanthocyanidins (a polyphenol and a flavonol), citrus bioflavonoid complex, rutin, amino acids, L-glycine, mucopolysaccharides, coenzyme Q-10, beta-carotene (carotenoid), and a dietary supplement (column 2 lines 64, column 3 lines 1-30 and 33-46).

Greenberg further disclose the composition strengthens the immune system (column 5 lines 26-28) and a method comprising administering the dietary supplement to a patient in need for such a treatment (one capsules 3 times daily for adults)(column 3 lines 49-50).

Greenberg therefore clearly anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-19, 20-22, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Vetvicka et al. (JANA, 2002, Vol. 5, No.2, p.5-9) and Ochao et al. (Journal of Parenteral & Enteral

Nutrition, 2001, Vol. 25, No. 1, p.23-29) and further in view of Birt et al. (Pharmacology & Therapeutics, 2001, Vol. 90, p.157-177).

As mentioned above, Greenberg teaches the limitations of claims 1-10, and 12-17.

Greenberg does not teach β -glucan (polysaccharide), L-arginine (amino acid), taxifolin and luteolin (flavonoids) and lycopene (carotenoid). However, Vetvicka et al. teach β -glucans, exhibit immunostimulating properties, including antibacterial and anti-tumor activities (Abstract, and p.5, 2nd column 1st paragraph).

Moreover, Ochoa et al. teach dietary supplementation of L-arginine (Abstract, p.24, 1st column 2nd paragraph).

Furthermore, Birt et al. teach flavones and isoflavones may play a prominent role in cancer prevention, and regulation of the host immune system. Birt et al. further teach luteolin and taxifolin (Abstract, p.168 2nd column 2nd paragraph).

Birt et al. further teach dietary intake of carotenoids including lycopene in relation to lung cancer occurrence (p.159, 2nd column 3rd paragraph).

Therefore, in view of the above teachings, it would have been obvious to one of ordinary skill in the art to modify the composition as taught by Greenberg by substituting the polysaccharide with β -glucan as taught by Vetvicka et al. and amino acid with L-arginine as taught by Ochoa et al, and the flavonoid with taxifolin as taught by Birt et al. The motivation as taught by Vetvicka would be the immunostimulating properties, including antibacterial and anti-tumor activities of β -glucan and as taught by Ochoa et al. the immunostimulatory properties of L-arginine, and as taught by Birt et al. the anticarcinogenic activity of flavonoids. The claims would have been obvious to one of

the ordinary skill in the art to combine the prior art teachings to obtain a composition to strengthen the immune response. As a person of ordinary skill has good reason to pursue, the known options within his or her technical grasp. In turn, because the composition as claimed has the properties predicted by the art, it would have been obvious to make the claimed dietary composition.

Claims 1-11, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Rayman, M. P. (previously cited, The Lancet, 2000, Vol. 356, p. 233-241).

Claims 1, 11, 32 and 33 are drawn to a composition comprising one plant protease and/or one animal protease, vitamins (having antioxidant activity), selenium-containing substances, one flavonoid, wherein the selenium-containing substance having antioxidant activity is sodium selenite, present in a concentration of 0.01 to 0.1% by weight.

As mentioned above, Greenberg teaches the limitations of claims 1-10.

Greenberg does not teach the selenium-containing substance is sodium selenite, in a concentration of 0.01 to 0.1% by weight. However, Rayman teaches supplementation of selenium as sodium selenite at 200µg per day has immunoenhancing effects and additionally cells of the immune system may have an important functional need for selenium (p.234 1st column 2nd to 4th paragraphs).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the composition as taught by Greenberg by substituting the selenium-containing substance with sodium selenite as taught by Rayman. The claim would have been

obvious since substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions about the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Kade Ariani
Examiner
Art Unit 1651